

REMARKS

I. Support for the Amendments to the Specification and Claims

The foregoing amendments are made to insert the required SEQ ID NO identifiers associated with various listed sequences and to accommodate the Examiner's objections concerning the description of Figure 7 and the use of the trademark AFFYMETIXTM, as well as to insert the "Cross-References to Related Applications."

Applicants submit herewith the Sequence Listing to include an amended sequence listing as part of this Application, along with an electronic copy and a Statement in Support of Filing and Submissions in Accordance with 37 CFR 1.821-1.825. Applicants wish to enter the Sequence Listing into the specification of the application and to renumber the pages containing the claims and abstract as needed. Applicants have added sequence identifiers to the specification and have included sequences originally listed in the specification in the sequence listing. In connection with the Sequence Listing submitted concurrently herewith:

1. the submission, filed herewith in accordance with 37 C.F.R. § 1.821(g), does not contain new matter, and
2. the content of the attached paper copy and the attached computer readable copy of the Sequence Listing, submitted in accordance with 37 C.F.R. § 1.821(c) and (e), respectively, are the same.

Support for the amendments to the specification and sequence listing can be found, e.g., in the specification as originally filed, which is a 35 U.S.C. §371 national stage of PCT application PCT/JP05/06444, filed March 25, 2005, which claims priority of Japanese Application Serial Number 2004-092064, filed March 26, 2004.

Additional support can be found, e.g., in the Examples (especially from page 96, line 25, to page 97, line 3) and in Figure 7.

No new matter has been added by virtue of the amendments to the specification.

Claims 1-41 were previously in the application. In the present Amendment, claims 15-16 have been amended, new claim 42 has been added, and claims 1-14 and 17-41 have been canceled. Claims 1-14 and 19-41 were previously withdrawn. Claims 1-14 and 17-41 been canceled without prejudice.

Applicants do not intend to relinquish subject matter by reason of these amendments or by reason of claim and/or species elections. Applicants reserve the right to pursue subject matter covered by the original language of claims 15-16 and canceled claims 1-14 and 17-41 in an appropriate divisional or continuation application.

Support for the amendments to claims 15-16 and for new claim 42 can be found in the original specification, including the Examples, and in the claims, including the previous language of the claims 15-16.

Additional support for amended claims 15-16 can be found, e.g., from page 5, line 23, to page 6, line 1; on page 6, lines 12-14; from page 13, line 20, to page 14, line 7; from page 42, line 19, to page 49, line 6; and in the Examples. Additional support for new claim 42 can be found, e.g., on page 2, lines 17-21; on page 42, lines 20-27; from page 42, line 19, to page 45, line 1; from page 46, line 35, to page 47, line 25; on page 59, lines 15-25; and in the Examples.

No new matter has been added by virtue of these amendments to the claims.

II. Status of the Claims

Claims 1-41 were originally in the application. Claims 1-41 were subject to restriction/election requirements. Claims 15-18 (Group V) and SEQ ID NO: 2 were elected. Claims 1-14 and 19-41 were withdrawn.

Claims 1-41 were previously in the application. In the present Amendment, claims 15-16 have been amended, new claim 42 has been added, and claims 1-14 and 19-41 have been canceled without prejudice.

Applicants do not intend to relinquish subject matter by reason of these amendments or by reason of claim and/or species elections. Applicants reserve the right to pursue subject matter covered by the original language of claims 15-16 and canceled claims 1-14 and 17-41 in an appropriate divisional or continuation application.

III. The Claim for Foreign Priority is Acknowledged

Applicants thank the Examiner for acknowledging the claim for foreign priority and for confirming receipt of all copies of certified copies of priority documents from the International Bureau.

IV. The Drawings are Accepted

Applicants thank the Examiner for accepting the drawings.

V. The Information Disclosure Statements are Acknowledged

Applicants thank the Examiner for acknowledging initialing the SB-08 forms for the Information Disclosure Statements filed on September 26, 2006; January 16, 2007; and October 23, 2007.

VI. The Objections to the Specification are Accommodated

The Examiner has objected to the specification. Applicants have amended the description of Figure 7 and have made the requested corrections to the trademark usage and the sequence listing in accordance with the Examiner's requests.

VII. The Objections to the Claims are Accommodated or Rendered Moot

The Examiner has objected to claims 15 and 17 for recitations of non-elected subject matter. Claim 15 has been amended to eliminate non-elected subject matter, and claim 17 has been canceled.

The Examiner has objected to claims 15-18 for the recitation of "represented by" and has suggested replacing this language with --of--. Applicants have amended claims 15-16 accordingly. Claims 17-18 have been canceled.

The Examiner has objected to a typographical error in claim 17. Claim 17 has been canceled.

VIII. The Rejection of Claims 1-2, 16-17, 20-26, 28, 31, 34, and 36-41 under 35 U.S.C. §112, Second Paragraph, is Accommodated in Part and Rendered Moot in Part

The Examiner has rejected claims 15-18 under 35 U.S.C. §112, second paragraph, for alleged indefiniteness.

Claims 17-18 have been canceled without prejudice, and the rejection is rendered moot with respect to these claims.

The Examiner has interpreted the phrase in claims 15 and 17 “the same or substantially the same amino acid sequence as the amino acid sequence represented by SEQ ID NO: 2” as “the same amino acid sequence as the amino acid sequence of SEQ ID NO: 2 or any amino acid sequence having 50% sequence identity with the amino acid sequence of SEQ ID NO: 2” (see p. 6). The Examiner appears to have interpreted this language in this manner throughout the Office Action (see pp. 7 *et seq.*).

Applicants respectfully disagree, but have amended claim 15 to read as follows:

15 (currently amended). A method of screening a prophylactic/therapeutic agent for respiratory diseases, which comprises using a protein comprising (a) the amino acid sequence of SEQ ID NO: 2 or (b) an amino acid sequence having at least 90% homology to the amino acid sequence of SEQ ID NO: 2, or a salt thereof, wherein said using of the protein comprises:

- (i) measuring the activity of the protein when a cell having an ability to produce the protein is cultured in the presence and absence of a test compound;

- (ii) comparing the measured activity of the protein in the presence of the test compound with the measured activity of the protein in the absence of the test compound; and
- (iii) selecting the compound which decreases the activity of the protein by at least about 20% as the prophylactic/therapeutic agent for respiratory diseases, wherein said activity is the cholesterol hydroxylation activity.

Without agreeing with the rejection, Applicants note that amended claim 15, as now pending, does not recite the phrase “substantially the same amino acid sequence.”

Claim 16 is dependent on underlying claim 15, and the same limitations also apply to this claim.

Thus, Applicants respectfully submit that remaining claims 15-16 fulfill the requirements of 35 U.S.C. §112, second paragraph, and request the Examiner’s reconsideration of these claims accordingly.

IX. The Rejection of Claims 15-18 under 35 U.S.C. §112, First Paragraph, for Alleged Failure to Comply with the Written Description Requirement

The Examiner has rejected claims 15-18 under 35 U.S.C. §112, first paragraph, for alleged failure to comply with the written description requirement. Applicants respectfully traverse this rejection, but have amended claim 15 as described above.

Claims 17-18 have been canceled, and the rejection is rendered moot with respect to these claims.

As noted above, the Examiner has interpreted the phrase in claims 15 and 17 “the same or substantially the same amino acid sequence as the amino acid sequence represented by SEQ

ID NO: 2” as “the same amino acid sequence as the amino acid sequence of SEQ ID NO: 2 or any amino acid sequence having 50% sequence identity with the amino acid sequence of SEQ ID NO: 2” (see pp. 6-7). The Examiner also rejects the claims for use of the phrase “its partial peptide.”

The Patent Office alleges in pertinent part:

In this case, the specification fails to describe any identification of structural characteristics or properties of the genus of proteins comprising [i] any partial peptide of the amino acid sequence of SEQ ID NO: 2, or [ii] any amino acid sequence having 50% sequence identity with the amino acid sequence of SEQ ID NO: 2 or its partial peptide, so that a skilled artisan can envision those proteins/peptides having a desired biological activity that are capable of being used in screening of a prophylactic/therapeutic agent for respiratory diseases from those that are not capable. Taken together, a method of using the genus of “proteins” or a kit comprising said genus of “proteins” as described above encompasses widely variant structures which may or may not have the desired biological function, and given the lack of additional representative species of said genus, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention. [Pp. 10-11.]

Applicants respectfully disagree, but have amended claim 15 as described, *supra*.

Without agreeing with the rejection, Applicants note that amended claim 15, as now pending, does not recite the phrase “substantially the same amino acid sequence,” nor does it recite the phrase “its partial peptide.”

Claim 16 is dependent on underlying claim 15, and the same limitations and reasoning also apply to this claim.

Thus, Applicants respectfully submit that remaining claims 15-16 fulfill the requirements of 35 U.S.C. §112, first paragraph, and request the Examiner’s reconsideration of these claims accordingly.

X. The Rejection of Claims 15-18 under 35 U.S.C. §112, First Paragraph, for Alleged Failure to Comply with the Enablement Requirement

The Examiner has rejected claims 15-18 under 35 U.S.C. §112, first paragraph, for alleged failure to comply with the enablement requirement. Applicants respectfully traverse this rejection, but have amended claim 15 as described above.

Claims 17-18 have been canceled, and the rejection is rendered moot with respect to these claims.

As noted above, the Examiner has interpreted the phrase in claims 15 and 17 “the same or substantially the same amino acid sequence as the amino acid sequence represented by SEQ ID NO: 2” as “the same amino acid sequence as the amino acid sequence of SEQ ID NO: 2 or any amino acid sequence having 50% sequence identity with the amino acid sequence of SEQ ID NO: 2” (see pp. 6-7). The Examiner also rejects the claims for use of the phrase “its partial peptide.”

The Patent Office reviews the *Wands* factors and alleges in pertinent part:

Claims 15-18 are rejected...because the specification, while being enabling for a method of screening a therapeutic agent for airway inflammation comprising using cholesterol 25-hydroxylase having the amino acid sequence as set forth in SEQ ID NO: 2, or a kit for screening a therapeutic agent for airway inflammation comprising cholesterol 25-hydroxylase having the amino acid sequence as set forth in SEQ ID NO: 2..., does not reasonably provide enablement for [1] a method of screening a prophylactic/therapeutic agent for respiratory diseases, which comprises using a protein comprising [i] the same amino acid sequence as the amino acid sequence of SEQ ID NO: 2, *its partial peptide*, or a salt thereof, or [ii] *any amino acid sequence having 50% sequence identity with the amino acid sequence of SEQ ID NO: 2, its partial peptide*, or

a salt thereof; and [2] a kit for screening a prophylactic/therapeutic agent for respiratory diseases, comprising a protein comprising [i] the same amino acid sequence as the amino acid sequence of SEQ ID NO: 2, *its partial peptide*, or a salt thereof, or [ii] *any amino acid sequence having 50% sequence identity with the amino acid sequence of SEQ ID NO: 2, its partial peptide*, or a salt thereof..... [Pp. 11-12; emphasis in original.]

Applicants respectfully disagree, but have amended claim 15 as described, *supra*.

Without agreeing with the rejection, Applicants note that amended claim 15, as now pending, does not recite the phrase “substantially the same amino acid sequence,” nor does it recite the phrase “its partial peptide.”

Claim 16 is dependent on underlying claim 15, and the same limitations and reasoning also apply to this claim.

Thus, Applicants respectfully submit that remaining claims 15-16 fulfill the requirements of 35 U.S.C. §112, first paragraph, and request the Examiner’s reconsideration of these claims accordingly.

XI. The Rejection of Claims 15-18 under 35 U.S.C. §102(b) for Alleged Anticipation by Russell

The Examiner has rejected claims 15-18 under 35 U.S.C. §102(b) for alleged anticipation by Russell et al. (Cholesterol 25-Hydroxylase, WO 200/23596 [published April 27, 2000]; “Russell”).

Claims 17-18 have been canceled, and the rejection is rendered moot with respect to these claims.

The Patent Office alleges, in pertinent part:

It is noted by the Examiner that the recitation of “for respiratory diseases,” in the preamble of Claims 15 and 17, has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone.... [Citation omitted.] [P. 19.]

Claim 15 has been amended to recite specific method steps with respect to respiratory diseases.

Because Russell does not disclose a link between the protein of SEQ ID NO: 2 and respiratory diseases, Applicants respectfully submit that amended claim 15 is not anticipated by Russell.

Claim 16 is dependent on underlying claim 15, and the same limitations and reasoning also apply to this claim.

Thus, Applicants respectfully submit that remaining claims 15-16 fulfill the requirements of 35 U.S.C. §102(b) and request the Examiner’s reconsideration of these claims accordingly.

CONCLUSION

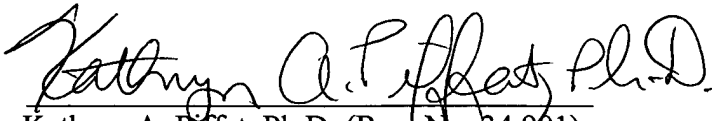
In view of the foregoing amendments and remarks, the present application is respectfully considered in condition for allowance. An early reconsideration and notice of allowance are earnestly solicited.

It is believed that all outstanding rejections have been addressed by this submission and that all the claims are in condition for allowance. If discussion of any amendment or remark made herein would advance this important case to allowance, the Examiner is invited to call the undersigned as soon as convenient.

Applicants hereby request a three-month extension of time for the Response and accompanying materials. If, however, a petition for an additional extension of time is required, then the Examiner is requested to treat this as a conditional petition for an additional extension of time and the Commissioner is hereby authorized to charge our deposit account no. 04-1105 for the appropriate fee. Although it is not believed that any additional fee (in addition to the fee concurrently submitted) is required to consider this submission, the Commissioner is hereby authorized to charge our deposit account no. 04-1105 should any fee be deemed necessary.

Respectfully submitted,

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